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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,754

09/23/2005

Michael Buschle

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EXAMINER

LE, EMILY M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,754	Applicant(s) BUSCHLE ET AL.	
	Examiner EMILY M. LE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 18, 19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 04/21/2008 is acknowledged.

Status of claims

2. Claims 1-12, 16-17 and 23-28 are canceled. Claims 13-15 and 18-22 are pending and under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-15, 18-19 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz et al.¹ in view of Egyed et al.²

In response to the rejection, Applicant argues that the references do not disclose the claimed specific combination. Applicant also argues that the combination of an influenza virus antigen, Peptide A, and an I-/U-ODN induced immune responses at levels that would not have been expected.

Applicant's arguments have been considered, however, it is not found persuasive. In view of Applicant's unexpected results argument, the rejection of claim

¹ Fritz et al. WO 02/32451 A1, published April 25, 2002.

² Egyed et al. WO 01/93903 A1, published December 13, 2001.

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20 is withdrawn. However, the rejection is maintained for claims 13-15, 18-19 and 21-22 for the observed unexpected results failed to evidence that unexpected results exists for the claimed genus of compositions. Applicant's unexpected result is limited to the sole species claimed in claim 20 and do not commensurate in scope with the invention encompassed by the other claims.

Regarding Applicant's argument that the references do not disclose the claimed specific combination, had the references disclosed the specific combination, the Office would have readily cited the reference(s) as anticipating the claimed invention.

However, the rejection is an obviousness rejection. In the instant case, *KSR* forecloses the argument that specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR*, 82 USPQ2d at 1396.

The claims are directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide, wherein the peptide and oligonucleotide have the structures described in the claims. Claim 14, which depends on claim 13, requires that the peptide be 11 amino acid residues in length by designating variable N to be 5. Claim 13, which depends on claim 13, requires the composition to further comprise alum adjuvant. Claim 18, which depends on claim 13, which requires the influenza antigen to be a hemagglutinin and neuraminidase antigens. Claim 19, which depends on claim 13, requires the composition to further comprise a polycationic peptide. Claim 21, which depends on claim 13, requires the composition to further comprise an oligonucleotide comprising a CpG motif. Claim 22, which depends on claim 13, requires

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the composition to comprise a polycationic peptide and an oligonucleotide comprising a CpG motif.

Fritz et al. teaches a composition comprising an antigen and a peptide. The antigen that Fritz et al. teaches includes the following viral antigens: influenza virus, HCV, HBV and HIV antigens. The peptide that Fritz et al. teaches has the same formula as those described in the claims of the instant patent application. The peptide of Fritz et al. has the following amino acid sequence: KLKL₅KLK.

Fritz et al. also suggests the addition of immunostimulating/immunogenic nucleic acid, such as an oligodeoxynucleotide containing deoxyinosine, an oligodeoxynucleotide containing deoxyuridine, an oligodeoxynucleotide containing the CpG motif or an inosine and cytidine containing nucleic acid molecule.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include immunostimulating/immunogenic nucleic acid, such as an oligodeoxynucleotide containing deoxyinosine, an oligodeoxynucleotide containing deoxyuridine, an oligodeoxynucleotide containing the CpG motif or an inosine and cytidine containing nucleic acid molecule in the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to modify the immune response induced by the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the immunostimulatory activities of said oligonucleotides are well known in the art.

While Fritz et al. does suggest the addition of an oligonucleotide comprising an inosine and cytidine, Fritz et al. was not specific on the length of the oligonucleotide. As recited in the claims, the oligonucleotide is about 5 to 151 nucleic acid residues in length. It should also be noted that Fritz et al. also suggests the addition of a polycationic peptide with the composition.

However, the deficiency noted in Fritz et al. is fully compensated by Egyed et al. Egyed et al. teaches an oligonucleotide comprising inosine and cytidine. The oligonucleotide Egyed teaches is a 26 nucleic acid residue oligomer, which is poly d(IC)₁₃. Egyed et al. additionally teaches that the oligonucleotide, in combination with a polycationic peptide, served as adjuvants to effectively deliver peptide antigens to the immune system.

Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made to combine the teachings of Fritz et al. and Egyed et al. to arrive at the claimed invention. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

Additionally, while Fritz et al. does suggest the addition of any known adjuvants, Fritz et al. does not specifically suggests alum Al(OH)₃. However, the deficiency noted in Fritz et al. is fully compensated by Egyed et al. Egyed et al. evidences the use of

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alum as an adjuvant at the time the invention was made. Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to add alum to the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition rendered obvious by Fritz et al. and Egyed et al. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

Lastly, while Fritz et al. does teaches of viral antigens, including antigens derived from the influenza virus, Fritz et al. does not specifically suggest that the antigen be a hemagglutinin or neuraminidase antigen. However, as Fritz et al. noted, any antigen can be used with the composition, and it is well known in the art that hemagglutinin or neuraminidase antigens can readily be attained from influenza virus. Thus, it would have been prima facie obvious for one of ordinary skill in the art to use hemagglutinin or neuraminidase antigens as the antigen in the composition of Fritz et al. One of ordinary skill in the art would have been motivated to do so to induce an immune response against the influenza virus. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the substitution of one antigen for another is routinely practiced in the art.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. In response to the provisional obviousness-type double patenting rejection, Applicant submits that if the provisional rejection is the sole outstanding rejection, the

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Office should withdraw the rejection and permit the application to issue, while citing MPEP 804(I)(B).

Applicant's submission has been noted, however, it is not found persuasive. The provisional obviousness-type double patenting rejection is NOT the only rejection remained. Additionally, it appears that Applicant has misconstrued the teachings of MPEP 804(I)(B). MPEP 804(I)(B)(1) provides:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

The instant application is not the earlier filed of the two pending applications in all of the issued provisional obviousness-type double patenting rejection. A terminal disclaimer is required to overcome the rejection.

7. Claims 13-15, 18-19 and 21-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 39 of copending Application No. 10/339442 in view of Egyed et al. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed invention is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide of 5-151 nucleic acid residues in length, wherein the peptide and oligonucleotide have the structures described in the claims.

The claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The peptide described in the copending patent application is the same as the peptide recited in the claimed invention. The oligonucleotide of the copending patent application has the same formula as those described in the claims of the instant patent, with the exception that the oligonucleotide recited in the copending application does not have a specific oligonucleotide length.

However, Egyed et al. teaches an oligonucleotide comprising inosine and cytidine. The oligonucleotide Egyed teaches is a 26 nucleic acid residue oligomer, which is poly d(IC)₁₃. Egyed et al. additionally teaches that the oligonucleotide, in combination with a polycationic peptide, served as adjuvants to effectively deliver peptide antigens to the immune system.

Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made to combine the teachings of Egyed et al. and the copending patent application to arrive at the claimed invention. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition of the copending patent application. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 13-15, 18-19 and 21-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 69 of copending Application No. 10/478771. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: It is not readily apparent if the peptide described in claim 69 of the copending application is the same as the peptide recited in the claims of the patent application. Thus, the Office turned to the specification to learn what Applicant intends to encompass by the peptide recited in the claims of the copending application. It is found that, in the copending patent application, Applicant intends to encompass a peptide that is the same as those recited in the claims of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 13-15, 18-19 and 21-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42 and 50 of copending Application No. 10/297555. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 42 of the copending patent application is directed to a composition comprising an antigen and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: Claim 42 of the copending patent application does not comprise a peptide. However, claim 50 of the copending patent application does suggest the addition of a peptide. The specification teaches that the peptide is immunostimulatory. Thus, it would have been prima facie obvious for one of ordinary skill in the art to include the peptide of claim 50 in the composition of claim 42. One of ordinary skill in the art would have been motivated to do so to modify the immune response induced by the composition of claim 42.

The difference between the claims of the copending patent application and the claims of the instant patent application is: It is not readily apparent if the peptide described in claim 50 of the copending application is the same as the peptide recited in the claims of the patent application. Thus, the Office turned to the specification to learn what Applicant intends to encompass by the peptide recited in the claims of the copending application. It is found that, in the copending patent application, Applicant intends to encompass a peptide that is the same as those recited in the claims of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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10. Claims 13-15, 18-19 and 21-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7148191 in view of Fritz et al. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In response to the rejection, Applicant argues that domination itself does not support a double patenting rejection and that it is separate from double patenting.

Applicant's argument has been considered, however, it is not found persuasive. While Applicant is correct to note that domination itself do not support a double patenting rejection, however, contrary to Applicant's conclusion, the domination is not the basis of the rejection. A proper double patenting rejection was issued on proper double patenting grounds, as outline in the rejection itself.

Additionally, Applicant argues unexpected results.

Applicant's argument of unexpected results has been noted, however, the observed unexpected results do not commensurate in scope with the invention encompassed by the rejected claims.

As previously presented, the claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: The polycationic peptide described in the

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copending patent application is not the same as the peptide recited in the claims of the instant patent application. However, at the time the invention was made, Fritz et al. teaches of polycationic peptides that have adjuvant properties. Thus, it would have been prima facie obvious for one of ordinary skill in the art to substitute the polycationic peptide of the copending patent application. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to produce an immunostimulatory composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the substitution of known alternatives are routinely practiced in the art.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./